

## CLINICAL STUDIES CENTER (CSC) OPERATING GUIDELINES

- 1) The CSC, located on the 11th floor of the VA medical center, is an area designated for conducting outpatient research studies. Research conducted in this space must adhere to VA approved guidelines. Managed by a CSC Director and a Medical Director, the CSC provides a controlled environment to perform a variety of studies. A satellite phlebotomy area is also available.

### **The Clinical Studies Center consists of the following:**

- a) Administrative offices: Director, Medical Director, Administrative Assistant
- b) Workstations for research coordinators and study monitors
- c) Storage room for research records of studies which have terminated.
- d) Four exam rooms: exam table, vital signs monitoring machine, X-ray view box, phlebotomy chairs, ophthalmoscope/otoscope, and network access
- e) Phlebotomy Services for research participants (see below)
- f) Interview room with table, chairs, and network access
- g) The laboratory room is utilized for specimen handling and storage. The room is equipped with:
  - I. Biosafety Cabinet
  - II. -80 °C Freezer
  - III. Refrigerator
  - IV. Refrigerated Centrifuge
  - V. Dry Ice
- h) **Study Records Storage:** The CSC provides long-term and short-term storage for study records
- i) **Office Request**
  - I. Contact the CSC Administrative Assistant or Director to request office space. Changes or additions to CSC office space require administrative approval
  - II. Provides basic office and medical supplies
  - III. **Room Reservations:** Contact the CSC Administrative Assistant for room reservations at ext. 4934.
    - a) Provide the following information when making a reservation:
      - a) Specify the type of room (exam/interview)
      - b) Requestor's name
      - c) Name of the study
      - d) Subject's name (or initials)
      - e) Date, time, and length of time needed

## **2) Expectations of Staff Using the CSC:**

- a) Greeting study participants in a timely fashion
- b) Notify the CSC of appointment cancellations
- c) Promote a professional atmosphere at all times
- d) Adhere to room scheduling procedures
- e) Keep study records in a secured area
- f) Maintain privacy and confidentiality at all times when dealing with Protected Health Information
- g) Maintain exam/interview rooms in an organized manner after use

## **3) When using the Laboratory Room**

- a) Follow safety guidelines as established by the Infectious Disease Control Department, OSHA, and Atlanta VA Laboratory & Biosafety
- b) Wear protective equipment (gloves, goggles, and apron) when handling any specimen
- c) Discard sharp objects and contaminated materials in appropriate containers
- d) Use the Biosafety cabinet when working with specimens
- e) Place an absorbent pad on work area, discard it after used and clean surface with Ethanol 70%
- f) Balance loads properly when using centrifuge
- g) Label specimens properly and do not leave them unattended
- h) Promptly remove specimens when finished and leave the centrifuge lid open
- i) Decontaminate immediately (see manual for instructions) if specimen vial breakage occurs

## **4) Utilizing Phlebotomy Services**

- a) All research draws should be entered in CPRS under Research Venipuncture. The only time when this is exempt is when the patient is having labs requested by a primary physician. There will be no need to input request via research venipuncture since labs are currently being drawn for patient care.
- b) The phlebotomist will ensure that specimens are taken to the hospital lab for processing several times per day. This can be in person, delegated to another CSC staff member or using escort services.

- c) The phlebotomist will be willing to work and communicate with study staff to ensure that specimens required for the study are handled properly and according to the research protocol.
- d) Research staff are responsible for storing samples or delivering information and/or other items related to the study.
- e) Research subjects may drop their specimens at the CSC satellite lab to be taken to the main laboratory.
- f) When the phlebotomist is not available for a day of work at the 11<sup>th</sup> floor satellite lab it becomes the responsibility of the accredited nurse coordinator to obtain the blood sample. If the nurse coordinator is not able to obtain the sample (not accredited or the patient is a difficult stick) the coordinator will ask another nurse coordinator to obtain the sample. If the sample cannot be obtained in this manner then the subject should go to the 2<sup>nd</sup> floor laboratory for phlebotomy services.